VI. Other Policy Decisions and Proposed Changes

A. Change in Services Covered Within the Scope of the OPPS

Section 1833(t)(1)(B) of the Act defines the term "covered OPD services" that are to be paid under the OPPS. "Covered OPD services" are "hospital outpatient services designated by the Secretary" and include "inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (i) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (ii) is not so entitled" (that is, "Part B-only" services). "Part B-only" services are certain ancillary services furnished to inpatients for which the hospital receives payment under Medicare Part B. Section 3110 of the Medicare Intermediary Manual and section 2255C of the Medicare Carriers Manual specify these services as diagnostic tests; X-ray and radioactive isotope therapy; surgical dressings, splints and casts; prosthetic devices; and limb braces and trusses and artificial limbs and eyes.

In the April 7, 2000 final rule, we included inpatient "Part B-only" services within the definition of services

payable under the OPPS (68 FR 18543). We have subsequently been approached by representatives of some hospitals that do not have outpatient departments and that, therefore, do no billing for Part B services except for a relatively few "Part B-only" services that they furnish to their inpatients. That is, the only bills these hospitals would ever submit for Part B payment are for the ancillary services designated as "Part B-only" services. These hospitals are concerned about the administrative burden and prohibitive costs they would incur if they were to change their billing systems to accommodate OPPS requirements solely to receive payment for "Part B-only" services.

We recognize that there are certain hospitals that do not have outpatient departments and that do not provide outpatient department services but that do provide inpatient services to Medicare beneficiaries. The only services these hospitals bill under OPPS are services furnished to inpatients. That is, these are special billings under the Part B-only benefit for limited ancillary services provided to beneficiaries who are admitted to the hospital as inpatients and who are not receiving services on an outpatient basis. We further

acknowledge that the expense of converting their billing systems to accommodate the OPPS is disproportionate to the Part B revenues that these hospitals receive. Therefore, we are proposing to revise §419.22 by adding subparagraph (r) to exclude from payment under the OPPS Part B-only services that are furnished to inpatients of hospitals that do no other billing for hospital outpatient services under Part B.

Under this proposed revision of the regulations, hospitals with outpatient departments would continue to bill under the OPPS for Part B-only services that they furnish to their inpatients. However, a hospital that does not have an outpatient department would be unable to bill under the OPPS for any Part B-only service the hospital furnished to its inpatients because those services would not fall within the scope of covered OPD services. If a hospital with no outpatient department is currently billing under the OPPS, the hospital would have to revert to its previous payment methodology for services furnished on or after January 1, 2002. That methodology would be an all-inclusive rate for hospitals paid that way prior to the

implementation of OPPS and reasonable cost for other hospitals.

We do not know at this time, and are not sure it would be possible to ascertain, the potential number of hospitals that would be affected by this regulatory change. However, we expect the financial impact on the program to be small, because this revised rule would apply only to the relatively few hospitals that are billing for the very limited range of Part B-only services for a small number of beneficiaries.

B. Categories of Hospitals Subject To and Excluded From the OPPS

In § 419.20(b) of the regulations, certain hospitals in Maryland that qualify under section 1814(b)(3) of the Act for payment under the State's payment system are excluded from the OPPS. Critical access hospitals (CAHs) that are paid under a reasonable cost-based system as required under section 1834(g) of the Act are also excluded. In addition, we stated in the April 7, 2000 final rule that the outpatient services provided by the hospitals of the Indian Health Services (IHS) will continue to be paid under separately established rates. We also

noted that we intended to consult with the IHS and develop a plan to transition these hospitals into OPPS. With these exceptions, the OPPS applies to all other hospitals that participate in the Medicare program.

It has been brought to our attention that under the statute, hospitals located in Guam, Saipan, American Samoa, and the Virgin Islands are excluded from the hospital inpatient PPS. These hospitals currently lack a charge structure for billing and, in some cases, are not equipped to prepare a cost report. They furnish very few services that would be subject to the OPPS. In addition, we believe that because of their distant locations, they incur costs that might not be adequately recognized by a PPS. Prior to implementation of the OPPS, each of the hospitals in Guam, American Samoa, Saipan, and the Virgin Islands had its own unique Medicare payment methodology for the outpatient services they furnish. In light of these factors, we are proposing to revise § 419.20 of the regulations by adding paragraph (b)(3) to exclude these hospitals from OPPS consistent with their treatment under inpatient PPS. In addition, we would revise that section to include the hospitals of the IHS so that it is clear that they are

excluded until we develop a plan to include them. We would note that it may also be possible to include the hospitals in the territories in the OPPS in the future.

C. Conforming Changes: Additional Payments on a Reasonable Cost Basis

Hospitals subject to the OPPS are paid for certain items and services that are outside the scope of the OPPS on a reasonable cost or other basis. Payments for the following services are made on a reasonable cost basis or otherwise applicable methodology:

a. The direct costs of medical education as described in § 413.86.

b. The costs of nursing and allied health programs as described in § 413.85.

c. The costs associated with interns and residents not in approved teaching programs as described in § 415.202.

d. The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based payment for teaching physicians under § 415.160.

e. The costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists

(certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c).

f. Bad debts for uncollectible deductible and coinsurance amounts as described in § 413.80(b).

g. Organ acquisition costs paid under Part B. Interim payments for these services are made on a biweekly basis and final payments are determined at cost report settlement.

We would revise § 419.2(c) to make conforming changes that reflect the exclusion of these costs from the OPPS rates.

D. Hospital Coding for Evaluation and Management (E/M) Services

In the April 7, 2000 final rule, we emphasized the importance of each facility accurately assessing the intensity, resource use, and charges for evaluation and management (E/M) services, in order to ensure proper reporting of the service provided. We stated that "the billing information that the hospitals report during the first years of implementation of the hospital outpatient

PPS will be vitally important to our revision of weights and other adjustments that affect payment in future years." (65 FR 18451)

We went on to state, "We realize that while these HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe nonphysician resources. However, . . . the same concept can be applied to each code in terms of the differences in resource utilization. Therefore, each facility should develop a system for mapping the provided services or combination of services furnished to the different levels of effort represented by the codes. . . . We will hold each facility accountable for following its own system for assigning the different levels of HCPCS codes. As long as the services furnished are documented and medically necessary and the facility is following its own system, which reasonably relates the intensity of hospital resources to the different levels of HCPCS codes, we will assume that it is in compliance with these reporting requirements as they relate to the clinic/emergency department visit code reported on the bill. Therefore, we would not expect to see a high degree of correlation

between the code reported by the physician and that reported by the facility. . . . We will work with the American Hospital Association and the American Medical Association to propose the establishment of appropriate facility-based patient visit codes. . . ."

We understand that facilities have developed several different systems for determining resource consumption to assign proper E/M codes. Some of these systems are based on clinical ("condition") criteria, and others are based on weighted scoring criteria. We continue to believe that proper facility coding of E/M services is critical for assuring appropriate payments. In order to achieve this, we are interested in developing and implementing a standardized coding process for facility reporting of E/M services. This process could include the use of current HCPCS codes or the establishment of new HCPCS codes in conjunction with guidelines for facility coding.

At this time, we are soliciting comments from hospitals and other interested parties on this issue. We will submit these comments to the APC Advisory Panel and ask for the Panel's recommendations regarding the development and implementation of a facility coding process

for E/M services. In order to ensure consideration by the Panel, comments must be received by November 1, 2001. Send comments regarding facility coding of E/M services to: OPPS-E/M coding, Centers for Medicare & Medicaid Services, Mailstop C4-05-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. CMS will review both the public comments and the recommendations from the Panel and propose a coding process in the proposed rule for 2003.

E. Annual Drug Pricing Update

Under the OPPS, we pay for drugs and biologicals in one of three ways.

1. Packaged Payment

As we explain in the April 7, 2000 final rule, we generally package the cost of drugs, biologicals, and pharmaceuticals into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished (65 FR 18450). No separate payment is made under the OPPS for drugs, biologicals, and pharmaceuticals whose costs are packaged into the APCs with which they are associated.

2. Transitional Pass-Through Payments for Eligible Drugs and Biologicals

As we explain in the April 7, 2000 final rule and in section VII of this preamble, the BBRA 1999 provided for special transitional pass-through payments for a period of 2 to 3 years for the following drugs and biologicals:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act;
- Current drugs and biologic agents used for treatment of cancer;
- Current radiopharmaceutical drugs and biological products; and
- New drugs and biologic agents in instances where the item was not being paid for as a hospital outpatient service as of December 31, 1996, and where the cost of the item is "not insignificant" in relation to the hospital outpatient PPS payment amount.

In this context, "current" refers to those items for which hospital outpatient payment was being made on August 1, 2000, the date on which the OPPS was implemented. A “new” drug or biological is a product that was not paid as a hospital outpatient service prior to January 1, 1997 and for which the cost is not insignificant in relation to the payment for the APC to which it is assigned.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs as the amount determined under section 1842(o) of the Act, that is, 95 percent of the applicable average wholesale price (AWP). Section 1833(t)(6)(D)(i) of the Act also sets the amount of additional payment for pass-through-eligible drugs and biologicals (the pass-through payment amount). The pass-through payment amount is the difference between 95 percent of the applicable AWP and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Therefore, as we explain in the April 7 final rule (65 FR 18481), in order to determine the correct pass-through payment amount, we first had to determine the cost that was packaged for the drug or biological within its related APC. In order to determine this amount, we used the following methodology, which we also explain in the April 7 final rule.

When we implemented the OPPS on August 1, 2000, costs for drugs and biologicals eligible for transitional pass-through payment were, to the extent possible, not included in the payment rates for the APC groups into which they had

been packaged prior to enactment of the BBRA 1999. That is, to the extent feasible, we removed from the APC groups into which they were packaged, the costs of as many of the pass-through eligible drugs and biologicals as we could identify in the 1996 claims data. Then, we assigned each drug and biological eligible for a pass-through payment to its own, separate APC group, the total payment rate for which was set at 95 percent of the applicable AWP.

Next, in order to establish the applicable beneficiary copayment amount and pass-through payment amount, we had to determine the cost of the pass-through eligible drug or biological that would have been included in the payment rate for its associated APC had the drug or biological been packaged. We used hospital acquisition costs as a proxy for the amount that would have been packaged, based on data taken from an external survey of hospital drug costs. (See the April 7, 2000 final rule (65 FR 18481))

We imputed the acquisition cost for the various drugs and biologicals in pass-through APCs by multiplying their applicable AWP by one of the following ratios. The following ratios are based on the survey data, and they

represent, on average, hospital drug acquisition cost relative to AWP:

- For drugs with one manufacturer (sole-source), the ratio of acquisition cost to AWP equals 0.68.
- For drugs with more than one manufacturer (multi-source), the ratio of acquisition cost to AWP equals 0.61.
- For drugs with more than one manufacturer and with generic competitors, the ratio of acquisition cost to AWP equals 0.43.

In accordance with section 1833(t)(7) of the Act, we base beneficiary copayment amounts for pass-through drugs only on that portion of the drug's cost that would have been included in the payment amount for an associated APC had the drug been packaged. Therefore, having determined the hospital acquisition cost of the drug based on the ratios described above, we multiply the acquisition cost by 20 percent to calculate the beneficiary copayment for the pass-through drug or biological APCs. Finally, to calculate the actual pass-through payment amount, we subtract from the applicable 95 percent of AWP the hospital acquisition cost less the beneficiary copayment amount.

To illustrate this payment methodology, consider a current sole source drug with an average wholesale price (AWP) of $100 per dose. Under section 1842(o) of the Act, the total allowed payment for the drug is $95, that is, 95 percent of AWP. We impute the cost of the drug based on survey data, which indicate hospital acquisition costs for this type of drug on average to be 68 percent of its AWP (or $68). In the absence of the pass-through provisions, this cost would be packaged into the APC payment for the procedure or service with which the drug or biological is furnished. Therefore, we define the beneficiary coinsurance as 20 percent of the imputed cost of $68, resulting in a copayment amount $13.60. The pass-through payment amount is $27 (the difference between 95 percent of AWP ($95) and the portion of the APC payment that is based on the cost of the drug ($68)). The total Medicare program payment in this example equals $81.40 (cost of the drug in the APC ($68) less beneficiary copay ($13.60) plus pass-through payment ($27)).

In this proposed rule, we are clarifying that, for purposes of calculating transitional pass-through payment amounts, we make no distinction between new and current

drugs and biologicals. Rather, we assume that drugs and biologicals defined as "new" under section 1833(t)(6)(A)(iv)(I) of the Act, that is, for which payment was not being made as of December 31, 1996, nonetheless replace or are alternatives to drugs, biologicals, or therapies whose costs would have been reflected in our 1996 claims data and, thus, have been packaged into an associated APC. Therefore, we assume that our imputed acquisition cost, based on the external survey data, represents that portion of the APC payment attributable to new as well as current drugs and biologicals. For that reason, we are discontinuing use of the payment status indicator "J" that we introduced in the November 13, 2000 final rule to designate a "new" drug/biological pass-through. Instead, we would assign payment status indicator "G" to both current and new drugs that are eligible for pass-through payment under the OPPS. (Addendum D lists the definition of the OPPS payment status indicators.)

3. Separate APCs for Drugs Not Eligible for Transitional Pass-Through Payment

There are some drugs and biologicals for which we did not have adequate cost data yet that are not eligible for

transitional pass-through payments. Beginning with the April 7, 2000 final rule, we created separate APCs for these drugs and biologicals. For example, we did not package into the emergency room visit APCs the various drugs classified as tissue plasminogen activators (tPAs) and other thrombolytic agents, which are used to treat patients with myocardial infarctions. Rather, we created individual APC groups for these drugs to allow separate payment so as not to discourage their use where appropriate.

We based the payment rate for these APCs on median hospital acquisition costs. To determine the hospital acquisition cost for the drugs, we imputed a cost using the same ratios of drug acquisition cost to AWP that we discuss in section VI.E.2. in connection with calculating acquisition costs for transitional pass-through drug payments. That is, we multiplied the AWP for the drug by the applicable ratio (sole or multi-source drug) based on data collected in an external survey of hospital drug acquisition costs.

We set beneficiary co-payment amounts for these drug APCs at 20 percent of the imputed acquisition cost. We use

status indicator "K" to denote the APCs for drugs, biologicals, and pharmaceuticals that are paid separately from and in addition to the procedure or treatment with which they are associated yet are not eligible for transitional pass-through payment. Refer to Addendum A to identify these APCs.

3. Annual Drug Pricing Update

a. Drugs Eligible for Pass-Through Payments

We used the AWPs reported in the Drug Topics Red Book to determine the payment rates for the pass-through drugs and biologicals. In the November 13, 2000 interim final rule (65 FR 67809), in response to a comment that we update the AWPs for pass-through drugs on a quarterly basis, we stated that, due to the complexity of the new payment system, we would be able to update the rates only on an annual basis. We also noted that the new rates would be effective for the quarter following the publication of the updated AWP values in the Red Book. It was our understanding that, although there are quarterly updates to the AWPs in the Red Book, the annual update is published in April of each year. It was our intention to update the AWPs for drugs each July 1, the quarter following the

annual publication, and we did use the April 2001 version of the Red Book to update the APC rates for drugs eligible for pass-through payments. The pass-through payment rates for drugs and biologicals updated for 2001 went into effect July 1, 2001 (Program Memorandum A-01-73, issued on June 1, 2001).

We found that doing an update for all the pass-through drugs and biologicals at mid-year was disruptive to both our computer systems and pricing software. Because it is now our understanding that even though the April publication is the annual printed version of the Red Book, there are quarterly updates available that we can use to update the AWPs. In fact, we have found that since the implementation of the pass-through payments in OPPS, many manufacturers have availed themselves of the Red Book quarterly update system to make frequent and large increases to their AWPs. Therefore, we do not believe it is necessary to wait until publication of the annual Red Book to do an update to the pass-through rates for drugs and biologicals to reflect the most recent AWPs.

Thus, we are proposing to update the APC rates for drugs that are eligible for pass-through payments in 2002

using the July 2001 or October 2001 version of Red Book (depending upon which is available when we develop the final rule). The updated rates effective January 1, 2002 would remain in effect until we implement the next annual update in 2003, when we would again update the AWPs based on the latest quarterly version of the Red Book. This would place the update of pass-through drug prices on the same calendar year schedule as the other annual OPPS updates.

b. Drugs in Separate APCs Not Eligible for Pass-Through Payments

We used the conversion factor published in the November 13, 2000 final rule (65 FR 67827) to update, effective January 1, 2001, the APC rates for the drugs that are not eligible for pass-through payments that are in separate APCs. We also made payment adjustments to these APC groups effective April 1, 2001, as required by section 401(c) of the BIPA, which sets forth a special payment rule that had the effect of providing a full market basket update in 2001.

For 2002, we propose to recalibrate the weights for the APCs for drugs that are not pass-through items and

make the other adjustments applicable to the APC groups that we discuss in sections III, IV, and VIII of this proposed rule.

F. Definition of Single-Use Devices

Our definition of a device eligible for pass-through payment includes a criterion whereby eligible devices are used for one patient only and are single use (65 FR 47674, August 3, 2000). In the November 13, 2000 interim final rule, we stated, in response to a comment, that additional pass-through payments would not be made for devices that are reprocessed or reused because they are not single-use items. We further indicated that hospitals submitting pass-through claims for these devices might be considered to be engaging in fraudulent billing practices (65 FR 67822).

Since publishing our November 13, 2000 rule, much has come to our attention regarding reprocessed single-use devices. Reprocessors and professional associations using reprocessed devices commented that, under certain circumstances, the FDA considers reprocessed devices to be single-use devices. The FDA corroborated that it considers previously used single-use devices that have been

appropriately reprocessed to be considered to be a single-use device. The reprocessing industry also indicated that reprocessed single use devices are of much lower cost to hospitals than original equipment manufactured single-use devices.

We have learned that the FDA published guidance for the reprocessing of single-use devices (FDA's "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," issued August 14, 2000). This document presents a phased-in regulatory scheme for reprocessed devices. As such, we are proposing to follow FDA's guidance on reprocessed single-use device. We would consider reprocessed single-use devices that are otherwise eligible for pass-through payment as part of a category of devices to be eligible for that payment if they meet FDA's most recent regulatory criteria on single-use devices. Also, reprocessed devices must meet any FDA guidance or other regulatory requirements in the future regarding single use. Reprocessed devices adhering to these guidelines would be considered as having met our criterion of approval or clearance by the FDA. We have met with and will continue to meet and coordinate with the FDA

concerning that Federal agency's definition and regulation of single-use devices.

Parties advise us that reprocessed devices reduce the costs to hospitals substantially. Therefore, we would expect that the hospital charges on claims submitted for pass-through payments for reprocessed single-use devices would reflect the lower cost of these devices.

G. Criteria for New Technology APCs

1. Background

In the April 7, 2000 final rule (68 FR 18477), we created a set of new technology APCs to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not addressed by the transitional pass-through provisions of the BBRA 1999. We indicated that the new technology APCs would be defined on the basis of costs and not the clinical characteristics of a service.

We initially established groups 0970 through 0984 as the new technology APCs with costs ranging from less than $50 to $6,000. The payment rate for each of these APCs is based on the midpoint of a range of costs. For example,

the payment for new technology APC 0974, which includes services that cost from $300 to $500, is set at $400.

The new technology APCs that were implemented on August 1, 2000 were populated with 11 new technology services. We state in the April 7, 2000 rule that we will pay for an item or service under a new technology APC for at least 2 years but no more than 3 years, consistent with the term of transitional pass-through payments. After that period of time, during the annual APC update cycle, we stated that we will move the item or service into the existing APC structure based on its clinical attributes and, based on claims data, its resource costs. For a new technology APC, the beneficiary coinsurance is 20 percent of the APC payment rate.

In the April 7, 2000 rule, we specified an application process and the information that must be supplied for us to consider a request for payment under the new technology APCs (65 FR 18478). We also described the five criteria we would use to determine whether a service is eligible for assignment to a new technology APC group. These criteria, which we are currently using, are as follows:

- The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the service could not have been adequately represented in 1996 data.

- The item or service does not qualify for an additional payment under the transitional pass-through payments provided for by section 1833(t)(6) of the Act as a current orphan drug, as a current cancer therapy drug or biological or brachytherapy, as a current radiopharmaceutical drug or biological product, or as a new medical device, drug, or biological.

- The item or service has a HCPCS code.

- The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act.

- The item or service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act.

2. Proposed Modifications to the Criteria and Process for Assigning Services to New Technology APCs

Based on the experience we have gained and data we have collected since publication of the April 7, 2000 final rule, we are proposing to revise--(a) the definition of

what is appropriately paid for under the new technology APCs; (b) the criteria for determining whether a service may be paid under the new technology APCs; (c) the information that we will require to determine eligibility for assignment to a new technology APC; and (d) the length of time we will pay for a service in a new technology APC.

a. Services Paid Under New Technology APCs

We propose to limit eligibility for placement in new technology APCs to complete services or procedures. That is, the following are not eligible for placement in a new technology APC: items, materials, supplies, apparatuses, instruments, implements, or equipment that are used to accomplish a more comprehensive service or procedure.

We would continue to exclude devices or any drug, biologic, radiopharmaceutical, product, or commodity for which payment could be made under the transitional pass-through provisions. We believe that the new technology APCs should be reserved for only those comprehensive services or procedures that are truly new. Individual components of a service or procedure that do not meet the transitional pass-through payment criteria should be incorporated into a current APC and as hospitals begin to

use the new items, supplies, or equipment the costs will become incorporated into the weight of the APC. To the extent possible, we believe that hospitals should be making the decision on what items, supplies, and equipment on the basis of efficiency and appropriate treatment of the patient. However, we believe it is appropriate to incorporate truly new services and procedures that replace much less expensive services or procedures into a new technology APC to afford access to our beneficiaries.

Furthermore, we wish to clarify that we do not consider that merely being a different approach to an existing treatment or procedure qualifies a service for assignment to a new technology APC. As new approaches to existing procedures and services are adopted and performed, we expect the costs associated with these variations and improvements to be reflected in the claims data that we use to annually update the APC relative weights.

b. Criteria for Assignment to New Technology APC

In light of the experience we have gained over the past year in reviewing requests for new technology and transitional pass-through status, developing criteria to define new medical services and technologies under the

inpatient PPS, and determining categories of new devices under the transitional pass-through provisions, we are proposing that the following criteria be used to determine whether a service be assigned to a new technology APC. These modifications are based on changes in data (we are no longer using 1996 data to set payment rates) and our continuing experience with the system of assigning new technology APCs.

- The service is one that could not have been adequately represented in the claims data being used for the most current annual payment update. (Current criterion based on 1996 data.)

- The service does not qualify for an additional payment under the transitional pass-through provisions. (This criterion is unchanged.)

- The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs. We believe it is unnecessary to assign a new service to a new technology APC if it may be appropriately placed in a current APC.

- The service falls within the scope of Medicare benefits under section 1832(a) of the Act. (This criterion is unchanged.)

- The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. (This criterion is unchanged.)

We would delete the criterion that the service must have a HCPCS code. In the absence of an appropriate HCPCS code, we would consider creating a HCPCS code that describes the procedure or service. These HCPCS codes would be solely for hospitals to use when billing under the OPPS.

c. Revision of Application for New Technology Status

We also propose to change the information that interested parties must submit to have a service or procedure considered for assignment to a new technology APC. Based on our experience over the past year in reviewing new technology APC applications, we believe that the criteria would better assist us in determining eligibility for these APCs than do the current criteria. Specifically, to be considered, we propose to require that requests include the following information:

- The name by which the service is most commonly known. We currently require only the trade/brand name.

- A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services as well as equipment, supplies, and devices, etc. This criterion would replace the criterion that requires a detailed description of the clinical application of the service. We believe we need a fuller description to help us understand how the service is furnished in hospitals.

- A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained. This would be a refinement of the current requirement for demonstrating FDA approval.

- A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location. This

criterion and the one that follows would help inform our analysis by providing us with medical contacts.

- An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.

- Information about the clinical use and efficacy of the service such as peer-reviewed articles. Again, this criterion would assist us in our clinical review of the procedure.

- The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS. This criterion and the three that follow are refinements of the current HCPCS requirement.

- A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for new technology status, would represent unbundling.

- A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.

- A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate.

- An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc. (This criterion is unchanged.)

- The name, address, and telephone number of the party making the request. (This criterion is unchanged.)

- Other information as CMS may require to evaluate specific requests. (This criterion is unchanged.)

d. Length of Time in a New Technology APC

We are also proposing to change the period of time during which a service may be paid under a new technology APC. Although section 1833(t)(6)(B) of the Act, as amended by section 201 of BBRA 1999, sets a 2 to 3 year period of

payment for transitional pass-through payments, this requirement does not extend to new technology APCs. In the April 7, 2000 final rule we stated our intention to adopt the same period of payment for new technology APCs for consistency. However, the experience we have gained during the first year of the OPPS has led us to the conclusion that a more flexible payment period would be preferable. Therefore, we are proposing to modify the time frame that we established for new technology APCs in the April 7, 2000 final rule and to retain a service within a new technology APC group until we have acquired adequate data that allow us to assign the service to a clinically appropriate APC. This would allow us to move a service from a new technology APC in less than 2 years if the data were available and would also allow us to retain a service in a new technology APC for more than 3 years if these data were not available.

We invite comment on the changes to the definition, criteria, application process, and timeframe that we are proposing for services and procedures that may qualify for assignment to a new technology APC under the OPPS.

VII. Transitional Pass-Through Payment Issues

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain innovative medical devices, drugs, and biologicals. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also required for new medical devices, drugs, and biologic agents that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments are to be made for at least 2 years but not more than 3 years.

Section 402 of BIPA, which was enacted on December 21, 2000, made several changes to section 1833(t)(6) of the Act. First, section 1833(t)(6)(B)(i) of the Act, as amended, requires us to establish by April 1, 2001, initial

categories to be used for purposes of determining which medical devices are eligible for transitional pass-through payments. We fulfilled this requirement through the issuance on March 22, 2001 of two Program Memoranda, Transmittals A-01-40 and A-01-41. These Program Memoranda can be found on the CMS homepage at www.hcfa.gov/pubforms/transmit/A0140.pdf and www.hcfa.gov/pubforms/transmit/A0141.pdf, respectively. We note that section 1833(t)(6)(B)(i)(II) of the Act explicitly authorizes the Secretary to establish initial categories by program memorandum.

Transmittal A-01-41 includes a list of the initial device categories and a crosswalk of all the item-specific C-codes for individual devices that were approved for transitional pass-through payments as of January 20, 2001 to the initial category code by which the device is to be billed beginning April 1, 2001.

Section 1833(t)(6)(B)(ii) of the Act also requires us to establish, through rulemaking, criteria that will be used to create additional categories, other than those established initially. The criteria for new categories are

the subject of a separate interim final rule with comment period, which will be published at a later date.

Transitional pass-through categories are for devices only; they do not apply to drugs or biologicals. The regulations governing transitional pass-through payments for eligible drugs and biologicals remain unchanged. The process to apply for transitional pass-through payment for eligible drugs and biological agents, including radiopharmaceuticals, can be found in the April 7, 2000 **Federal Register** (65 FR 18481) and on the CMS web site at http://www.hcfa.gov/medlearn/appdead.htm. If we revise the application instructions in any way, we will post the revisions on our web site and submit the changes for the Office of Management and Budget (OMB) review under the Paperwork Reduction Act.

B. Discussion of Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an "applicable percentage" of projected total payments under the hospital OPPS. For a year before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is

specified by the Secretary up to 2.0 percent. If the Secretary estimates before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a (prospective) uniform reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded.

In order to prepare for making an estimate, we have constructed an extensive database that includes outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000. We are also collecting device cost and utilization data that were provided by manufacturers. We are extracting device cost and utilization data from applications for pass-through status submitted by manufacturers, hospitals, specialty societies, and other entities. In their applications for pass-through status, manufacturers have supplied information on the expected cost to hospitals of devices and the procedures with which the devices are commonly used.

The information that we have collected thus far suggests that a significant pro rata reduction could be required for 2002 in order to meet the statutory limit on the amount of the pass-through payments. Given the potential magnitude of the reductions, we are reviewing our data and methodology to identify any flaws or weaknesses in them and to determine whether a significant reduction would actually be required under the statute. We are also considering the appropriateness of a number of possible alternative approaches to different technical aspects of estimating payments that would have the effect of minimizing the amount of any potential reduction in these payments. Below is a discussion of the methodology that we contemplate employing in developing our estimate.

We are considering a number of possible approaches to different technical aspects of estimating payments. As is always the case in making these types of estimates, it is necessary to make a number of assumptions in interpreting the data. We are tentatively contemplating using the following assumptions and techniques in developing our methodology:

1. Data and Methodology

We plan to base the estimate of 2002 pass-through expenditures on the claims we would use to set payment rates for 2002, 2001 pass-through amounts for drugs and radiopharmaceuticals, and device cost and use data from pass-through applications submitted by manufacturers, hospitals, specialty societies, and other entities. Projections to CY 2002 would employ price, volume, and service-mix inflators consistent with our baseline for OPPS spending. Estimates for drugs, radiopharmaceuticals, and devices would be made separately and combined for the final projection of pass-through spending.

2. Drugs and Biologicals

We would identify those drugs eligible for pass-through status that have been separately billed to the Medicare program on the claims that we intend to employ for the estimate. We would multiply the frequency of use for each of these drugs (that is, the number of line items multiplied by the number of units billed as shown in the claims data) by its 2001 pass-through payment amount. If any drugs are not reflected in the claims data, we would make an appropriate adjustment. Such an adjustment might

take into account the extent to which the non-coded items are classified as orphan drugs and therefore would likely be used infrequently.

3. Radiopharmaceutical Drugs and Biological Products

Similar to the drug estimate, we would identify those radiopharmaceuticals eligible for pass-through status that were separately billed to Medicare in the claims data file. We would estimate expenditures for these radiopharmaceuticals directly as described above. For radiopharmaceutical drugs, we would multiply the frequency of use for each item by the 2001 pass-through amount. We would estimate expenditures for the remaining items by using the frequency counts for all nuclear medicine procedures not billed with one of these radiopharmaceuticals.

4. Medical Devices

We would estimate the transitional pass-through payments attributable to devices by linking the frequencies for all device-related procedures in the claims data file with the cost and use data supplied by the manufacturers or other entities as part of their applications for pass-through status. We would match each device eligible as of

January 2001 with the procedures with which it would be used. We would then calculate an average cost for each device or device package associated with a procedure.

The statute requires that we calculate transitional pass-through payments for devices by adjusting the hospital's charge for the device to cost and then subtracting an amount that reflects the device costs already included in the payment for the associated APC. As we explained in the April 7, 2000 final rule (65 FR 18481) we were not able to implement these subtractions at the time of implementation of the system. For 2001, as we explain in section III.C. of this preamble, we made these deductions for pacemakers and neurostimulators but not other devices because it was not feasible to make the deductions for the other devices at that time. As also explained in section III.C., we are proposing to make these subtractions for most other devices beginning in 2002. For the purpose of doing this estimation, we would deduct these amounts from each device package before multiplying that cost by the procedure frequencies. In total, we project the deductions to be $450 million. (See section III.C. for a discussion of how we calculated the deductions.)

5. Projecting to 2002

After making the three estimates as determined above, we plan to project prices and quantities in the estimates to 2002 using actuarial projections of price, volume, and service increase consistent with the OPPS baseline. We would add the three separate results for drugs, radiopharmaceuticals, and devices to determine an estimate of total pass-through spending.

C. Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups

1. Background

As discussed above in section II.C.1. of this preamble, in the November 13, 2000 interim final rule (65 FR 67806 and 67825), we explained that we originally excluded costs in revenue codes 274 (Prosthetic/orthotic devices), 275 (Pacemaker), and 278 (Other implants) from the calculation of APC payment rates because, before enactment of the BBRA 1999, we had proposed to pay for implantable devices outside of the OPPS and after the enactment of the BBRA, it was not feasible to revise our database to include these revenue codes in developing the April 7, 2000 final rule. We were able to make the necessary revisions and

adjustments in time for implementation on January 1, 2001. When we packaged costs from these revenue codes to recalculate APC rates for 2001, to comply with the BBRA 1999 requirement, the median costs for a handful of procedures related to pacemakers and neurostimulators significantly increased. Therefore, we restructured the affected APCs to account for these changes in procedure level median costs.

Under section 1833(t)(6)(D)(ii) of the Act, as added by the BBRA 1999 and redesignated by BIPA, the amount of additional payment for an eligible device is the amount by which the hospital's cost exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. Thus, beginning January 1, 2001, for eligible devices, we deducted from transitional pass-through payments the dollar increase in the rates for the new APCs for procedures associated with the devices. Effective April 1, 2001, we revised our policy to subtract the dollar amount from the otherwise applicable pass-through payment for each category of device. The dollar amount subtracted in 2001 from transitional pass-through payments for affected categories of devices is as follows:

Table 4 - CY 2001 Reductions to Pass-Through Payments to Offset Device-Related Costs Packaged in Associated APC Groups

For Item Billed Under HCPCS Code. . . .	Subtract from the Pass-Through Payment the Following Amount:
C1767 Generator, neurostimulator (implantable)	$643.73
C1778 Lead, neurostimulator (implantable)	$501.27
C1785 Pacemaker, dual chamber, rate-responsive (implantable)	$2,843.00
C1786 Pacemaker, single chamber, rate-responsive (implantable)	$2,843.00
C1816 Receiver and/or transmitter, neurostimulator (implantable)	$537.83
C2619 Pacemaker, dual chamber, non rate-responsive (implantable)	$2,843.00
C2620 Pacemaker, single chamber, non rate-responsive (implantable)	$2,843.00

The increase in certain APC rates for device costs on January 1, 2001 was offset by the simultaneous reduction of the associated pass-through payments. Payments for the procedures in the affected APCs that did not include a pass-through device increased for 2001 and for procedures

that did include devices, total payment for the procedure plus the device or devices did not change.

For 2002, in this proposed rule we are estimating the portion of each APC rate that could reasonably be attributed to the cost of associated devices that are eligible for pass-through payments. This amount will be deducted from the pass-through payments for those devices as required by the statute. Since the deductions to the pass-through payments for costs included in APCs for 2002 are included in the recalibration of the weights and the fixed pool of dollars for outpatient services, the total payment for the procedure plus device or devices will be reduced rather than remain constant as they did in 2001.

2. Proposed Reductions for 2002

First, we reviewed the APCs to determine which of them contained services that are associated with a category of devices eligible for a transitional pass-through payment. We then estimated the portion of the costs in those APCs that could reasonably be attributed to the cost of pass-through devices as follows:

- For each procedure associated with a pass-through device or devices, we examined all single-service bills

(that is, bills that include services payable only under one APC) to determine utilization patterns for specific revenue centers that would reasonably be used for device-related charges in revenue codes 272 (sterile supplies), 275 (pacemakers), and 278 (other implants).

- We removed the costs in those revenue codes to calculate a cost for the bill net of device-related costs (reduced cost). For example, the average bill cost (in 1999-2000 dollars) for insertion of a cardiac pacemaker (CPT 33208) was $5,733. The average cost associated with revenue code 275 was $4,163, so the reduced cost for the procedure was $1,570. We calculated the ratio of the reduced cost ($1,570) to the full bill costs ($5,733), and we applied that ratio to the costs on any bills for CPT 33208 that did not use revenue code 275 to establish reduced cost at the procedure code level across all claims.

- To determine the reduced cost at the APC level and that portion of the APC payment rate associated with device costs, we calculated the median cost of the reduced cost bills for each relevant APC. For this calculation of the median, we allowed the full costs of bills for services in the APC that were not associated with pass-through devices.

- We calculated, for the APC, the percentage difference between the APC median of full cost or unreduced bills and the APC median where some or all of the bills had reduced costs. We applied this percent difference to the proposed APC payment rate in order to calculate the share of that rate attributable to the device or devices associated with procedures in the APC. In Table 5, we show the amount that we propose to subtract from the pass-through payment for an eligible device that is billed with the related APCs.

Table 5-Proposed Reduction to Pass-Through Payment to Offset Device-Related Costs Packaged in Associated APC Groups

APC	Description	Percent Differences	Device-Related Cost to be Subtracted from Pass-Through Payment for Eligible Device
00032	Insertion of Central Venous/Arterial Catheter	20.11	$73

00080	Diagnostic Cardiac Catheterization	9.99	$164
00081	Non-Coronary Angioplasty or Atherectomy	27.06	$303
00082	Coronary Atherectomy	6.95	$462
00083	Coronary Angioplasty	19.85	$506
00088	Thrombectomy	10.86	$161
00089	Insertion/Replacement of Permanent Pacemaker and Electrodes	72.69	$3,052
00090	Insertion/Replacement of Pacemaker Pulse Generator	77.13	$2,877
00104	Transcatheter Placement of Intracoronary Stents	11.64	$422
00106	Insertion/Replacement/ Repair of Pacemaker and/or Electrodes	79.55	$640
00107	Insertion of Cardioverter-Defibrillator	81.69	$6,449

0108	Insertion/Replacement/ Repair of Cardioverter-Defibrillator Leads	71.16	$5,768
0122	Level II Tube Changes and Repositioning	24.92	$72
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	7.35	$61
0152	Percutaneous Biliary Endoscopic Procedures	12.05	$107
0154	Hernia/Hydrocele Procedures	8.80	$108
0182	Insertion of Penile Prosthesis	57.22	$2,500
0185	Removal or Repair of Penile Prosthesis	56.82	$1,652
0202	Level VIII Female Reproductive Procedures	25.02	$503
0222	Implantation of Neurological Device	75.70	$4,330

0223	Implantation of Pain Management Device	79.51	$359
0225	Implantation of Neurotransmitter Electrodes	67.25	$1,154
0227	Implantation of Drug Infusion Device	80.23	$3,871
0229	Transcatheter Placement of Intravascular Shunts	35.46	$1,083
0246	Cataract Procedures with IOL Insert	12.87	$146

VIII. Conversion Factor Update for CY 2002

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis.

Section 1833(t)(3)(C)(iv) of the Act, as redesignated by section 401 of the BIPA, provides that for 2002, the update is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point. Further, section 401 of the BIPA

increased the conversion factor for 2001 to reflect an update equal to the full market basket percentage increase amount.

The most recent forecast of the hospital market basket increase for FY 2002 is 3.3 percent. To set the proposed OPPS conversion factor for 2002, we increased the 2001 conversion factor of $50.080, which reflects the BIPA provision of the full market basket update, by 2.3 percent, that is, the 3.3 percentage increase minus 1 percentage point.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for 2002 to ensure that the revisions we are proposing to update the wage index are made on a budget-neutral basis. A budget neutrality factor of 0.9924 was calculated for wage index changes by comparing total payments from our simulation model using the proposed FY 2002 hospital inpatient PPS wage index values to those payments using the current (FY 2001) wage index values.

The increase factor of 2.3 percent for 2002 and the required wage index budget neutrality adjustment of 0.9924 result in a proposed conversion factor for 2002 of $50.842.

IX. Summary of and Responses to MedPac Recommendations

The Medicare Payment Advisory Commission (MedPAC) offered several recommendations dealing with the OPPS in its March 2001 Report to Congress. Below we summarize each recommendation and respond to it.

MedPAC Recommendation: MedPAC has offered two recommendations regarding the update to the conversion factor in the OPPS. The first recommendation is that the Secretary should not use an expenditure target to update the conversion factor. The second recommendation is that Congress should require an annual update of the conversion factor in the OPPS that is based on the relevant factors influencing the costs of efficiently providing hospital outpatient care, and not just the change in input prices.

Response: Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor annually. Under section 1833(t)(3)(C)(iv) of the Act the update is equal to the hospital market basket percentage increase applicable under the hospital inpatient PPS, minus one percentage point for the years 2000 and 2002. The Secretary has the authority under section 1833(t)(3)(C)(iv) of the Act to substitute a market basket that is specific

to hospital outpatient services. Finally, section 1833(t)(2)(F) of the Act requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient services, and section 1833(t)(9)(C) of the Act authorizes the Secretary to adjust the update to the conversion factor if the volume of services increased beyond the amount established under section 1833(t)(2)(F) of the Act.

In the September 8, 1998 proposed rule on the OPPS, we indicated that we were considering the option of developing an outpatient-specific market basket and invited comments on possible sources of data suitable for constructing one (63 FR 47579). We received no comments in response to this invitation, and we therefore announced in the April 7, 2000 final rule that we would update the conversion factor by the hospital inpatient market basket increase, minus one percentage point, for the years 2000, 2001, and 2002 (65 FR 18502). As required by section 401(c) of the BIPA, we made payment adjustments effective April 1, 2001 under a special payment rule that has had the effect of providing a full market basket update in 2001. We are, however, working with a contractor to study the option of developing

an outpatient-specific market basket and would welcome comments and recommendations regarding appropriate data sources. We will also study the feasibility of developing appropriate adjustments for factors that influence the costs of efficiently providing hospital outpatient care, such as productivity increases and the introduction of new technologies, and the availability of appropriate sources of data for calculating the factors.

In the September 8, 1998 proposed rule on the OPPS, we proposed employing a modified version of the physicians' sustainable growth rate system (SGR) as an adjustment in the update framework to control for excess increases in the volume of covered outpatient services (63 FR 47586-47587). In response to comments on this proposal, we announced in the April 7, 2000 final rule that we had decided to delay implementation of a volume control mechanism, and to continue to study the options with a contractor (65 FR 18503). We will take MedPAC's recommendation into consideration in making a decision, and before implementing volume control mechanism we will publish a proposed rule with an opportunity for public comment.

MedPAC Recommendation: MedPAC recommends that the

Secretary should develop formalized procedures in the OPPS for expeditiously assigning codes, updating relative weights, and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies.

Response: Beginning with the April 7, 2000 final rule implementing the OPPS, we have outlined a comprehensive process to recognize the costs of new technology in the new system. One component of this process is the provision for pass-through payments for devices, drugs, and biologicals (see the discussion in conjunction with the next MedPAC recommendation). The other component is the creation of new APC groups to accommodate payment for new technology services that are not eligible for transitional pass--through payments. We assign new technology services that cannot be appropriately placed within existing APC groups to new technology APC groups, using costs alone (rather than costs plus clinical coherence) as the basis for the assignment. We describe revised criteria for assignment to a new technology group in section VI.G. of this preamble. When it is necessary, creation of new technology APC groups involves establishment of new codes. New codes are

established through a well-ordered process that operates on an annual cycle. The cycle starts with submission of information by interested parties no later than April 1 of each year and ends with the announcement of new codes in October. As we stated previously, in the absence of an appropriate HCPCS code, we would consider creating a HCPCS code that describes the procedure or service. These codes would be solely for hospitals to use when billing under the OPPS.

We have also provided a mechanism for moving these services from the new technology APCs to clinically related APCs as part of the annual update of the APC groups. As described in section VI of this preamble, a service is retained within a new technology APC group until we have acquired adequate data that allow us to assign the service to an appropriate APC. We use the annual APC update cycle to assign the service to an existing APC that is similar both clinically and in terms of resource costs. If no such APC exists, we create a new APC for the service.

MedPAC Recommendation: MedPAC recommends that pass-through payments for specific technologies should be made in the OPPS only when a technology is new or substantially

improved and adds substantially to the cost of care in an APC. MedPAC believes that the definition of "new" should not include items whose costs were included in the 1996 data used to set the OPPS payment rates.

Response: The statute requires that, under the OPPS, transitional pass-through payments are made for certain drugs, devices, and biologicals. The items designated by the statute to receive these pass-through payments include the following:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

- Current drugs and biologicals used for the treatment of cancer, and brachytherapy and temperature monitored cryoablation devices used for the treatment of cancer.

- Current radiopharmaceutical drugs and biologicals.

- New drugs and biologicals in instances in which the item was not being paid as a hospital outpatient service as of December 31, 1996, and when the cost of the item is "not insignificant" in relation to the OPPS payment amount.

- Effective April 1, 2001, categories of Medical

devices when the cost of the category is “not insignificant" in relation to the OPPS payment amount.

We are publishing a separate interim final rule in which we lay out the criteria for establishing categories of devices eligible for pass-through payments.

Section 1833(t)(6) of the Act provides that once a category is established, a specific device may receive a pass-through payment for 2 to 3 years if the device is described by an existing category, regardless of whether it was being paid as a hospital outpatient service as of December 31, 1996 or its cost meets the "not insignificant" criterion. Thus, the statute allows for certain devices that do not meet MedPAC’s recommended limitation on a “new” device to receive transitional pass-through payments. However, no categories are created on the basis of devices that were paid for on or before December 31, 1996. That is, while devices paid for on or before December 31, 1996 can be included in a category, we would establish a category only on the basis of devices that were not being paid as hospital outpatient services as of December 31, 1996.

MedPAC Recommendation: MedPAC recommends that pass-through payments for specific technologies in the OPPS should be made on a budget-neutral basis and that the costs of new or substantially improved technologies should be factored into the update of the outpatient conversion factor.

Response: The statute requires that the transitional pass-through payments for drugs, devices, and biologicals be made on a budget neutral basis. Estimated pass-through payments are limited under the statute to 2.5 percent (and up to 2.0 percent for 2004 and thereafter) of estimated total program payments for covered hospital outpatient services. We adjust the conversion factor to account for the proportion of total program payments for covered hospital outpatient services, up to the statutory limit, that we estimate will be made in pass-through payments. As we have discussed in response to MedPAC's recommendation concerning an update framework for the OPPS conversion factor, we will study the feasibility of including appropriate adjustments for factors, including introduction of new technologies, that influence the costs of

efficiently providing hospital outpatient care within such a framework.

MedPAC Recommendation: MedPAC recommends that the Congress should continue the reduction in outpatient coinsurance to achieve a 20 percent coinsurance rate by 2010.

Response: For most services that Medicare covers, the program is responsible for 80 percent of the total payment amount, and beneficiaries pay 20 percent. However, under the cost-based payment system in place for outpatient services before the OPPS, beneficiaries paid 20 percent of the hospital's charges for these services. As a result, coinsurance was often more than 20 percent of the total payment amount for the services.

The BBA established a formula under the OPPS that was designed to reduce coinsurance gradually to 20 percent of the total payment amount. Under this formula, a national copayment amount was set for each service category, and that amount is to remain frozen as payment rates increase until the coinsurance percentage falls to 20 percent for all services. On average, beneficiaries have paid about 16

percent less in copayments for hospital outpatient services during 2000 under the OPPS than they would have paid under the previous system. However, it is true that the coinsurance remains higher than 20 percent of the Medicare payment amount for many services.

Subsequent legislation has placed caps on the coinsurance percentages to speed up this process. Specifically, section 111 of BIPA amended section 1833(t)(8)(C)(ii) of the Act to reduce beneficiary coinsurance liability by phasing in a cap on the coinsurance percentage for each service. Starting on April 1, 2001, coinsurance for a single service furnished in 2001 cannot exceed 57 percent of the total payment amount for the service. The cap will be 55 percent in 2002 and 2003, and will be reduced by 5 percentage points each year from 2004 to 2006 until coinsurance is limited to 40 percent of the total payment for each service. The underlying process for decreasing coinsurance will also continue during this period (see discussion in section IV.A. of this preamble). However, MedPAC projects that under current law, it would take until 2029 to reach the

goal of 20 percent coinsurance for all services.

We agree with MedPAC's goal of continuing the reduction in outpatient coinsurance, and we would welcome enactment of a practical measure to do so.

X. Provider-Based Issues

A. Background and April 7, 2000 Regulations

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). Since the beginning of the Medicare program, some providers, which we refer to as "main providers," have functioned as a single entity while owning and operating multiple departments, locations, and facilities. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare for those services.

The regulations at § 413.65 define provider-based status as "the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section."

Section 413.65(b)(2) states that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations at § 413.65(d). Among these criteria are the requirements that the main provider and the facility must have common licensure (when appropriate), the facility must operate under the ownership and control of the main provider, and the facility must be located in the immediate vicinity of the main provider.

The effective date of these regulations was originally set at October 10, 2000, but was subsequently delayed and is now in effect for cost reporting periods beginning on or after January 10, 2001. Program instructions on provider-based status issued prior to that date, found in Section 2446 of the Provider Reimbursement Manual - Part 1 (PRM-1), Section 2004 of the Medicare State Operations Manual (SOM), and CMS Program Memorandum (PM) A-99-24, will apply to any facility for periods before the new regulations become applicable to it. (Some of these instructions will not be applied because they have been superseded by specific

legislation on provider-based status, as described in item C below).

B. Provider-Based Issues/Frequently Asked Questions

Following publication of the April 7, 2000 final rule, we received many requests for clarification of policies on specific issues related to provider-based status. In response, we published a list of "Frequently Asked Questions" and the answers to them on the CMS web site at www.hcfa.gov/medlearn/provqa.htm. (This document can also be obtained by contacting the CMS (Formerly, HCFA) Regional Office.) These Qs and As did not revise the regulatory criteria, but do provide subregulatory guidance for their implementation.

C. Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554)

On December 21 2000, the Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554) was enacted. Section 404 of BIPA contains provisions that significantly affect the provider-based regulations at § 413.65. Section 404 includes a grandfathering provision for facilities treated as provider-based on October 1, 2000; alternative criteria for meeting the geographic

location requirement; and criteria for temporary treatment as provider-based.

1. Two-Year "Grandfathering"

Under section 404(a) of BIPA, any facilities or organizations that were "treated" as provider-based in relation to any hospital or CAH on October 1, 2000 will continue to be treated as such until October 1, 2002. For the purpose of this provision, we interpret "treated as provider-based" to include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, existing provider-based facilities and organizations may retain that status without meeting the criteria in the regulations under §§ 413.65(d), (e), (f), and (h) until October 1, 2002. These provisions concern provider-based status requirements, joint ventures, management contracts, and services under arrangement. Thus, the provider-based facilities and organizations affected under section 404(a) are not required to submit an application for or obtain a provider-based status determination in order to continue

receiving reimbursement as provider-based during this period.

These provider-based facilities and organizations will not be exempt from the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements for provider-based facilities and organizations (revised § 489.24(b) and new § 489.24(i)) or from the obligations of hospital outpatient departments and hospital-based entities in § 413.65(g), such as the requirement that off-campus facilities provide written notices to Medicare beneficiaries of coinsurance liability. These requirements become effective for hospitals on the first day of the hospital's cost reporting period beginning on or after January 10, 2001.

We are aware that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to provider-based facilities and organizations. We intend to re-examine these regulations and, in particular, reconsider the appropriateness of applying EMTALA to off-campus locations. At the same time, we want to assure that those departments that Medicare pays as hospital-based departments are appropriately integrated with the hospital as a whole. We

intend to publish a proposed rule to address these issues more fully.

2. Geographic Location Criteria

Section 404(b) of BIPA provides that those facilities or organizations that are not included in the grand-fathering provision at section 404(a) are deemed to comply with the "immediate vicinity" requirements of the new regulations under § 413.65(d)(7) if they are located not more than 35 miles from the main campus of the hospital or critical access hospital. Therefore, those facilities located within 35 miles of the main provider satisfy the immediate vicinity requirement as an alternative to meeting the "75/75 test" under § 413.65(d)(7).

In addition, BIPA provides that certain facilities or organizations are deemed to comply with the requirements for geographic proximity (either the "75/75 test" or the "35-mile test") if they are owned and operated by a main provider that is a hospital with a disproportionate share adjustment percentage greater than 11.75 percent and is (1) owned or operated by a unit of State or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of State or

local government, or (3) a private hospital that has a contract with a state or local government that includes the operation of clinics of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare or Medicaid.

These geographic location criteria are permanent. While those facilities or organizations treated as provider-based on October 1, 2000 are covered by the two-year grand-fathering provision noted above, the geographic location criteria at section 404(b) of BIPA and the regulations at § 413.65(d)(7) will apply to facilities or organizations not treated as provider-based as of that date, effective with the hospital's cost reporting period beginning on or after January 10, 2001. Beginning October 1, 2002, these criteria will also apply to the grandfathered facilities.

3. Criteria for Temporary Treatment as Provider-Based

Finally, section 404(c) of BIPA also provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000 and before October 1, 2002 may not be treated as not having

provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively for noncompliance with the provider-based criteria once a request for a determination during that time period has been made. For hospitals that do not qualify for grandfathering under section 404(a), until a uniform application is available, a request for provider-based status should be submitted to the appropriate CMS Regional Office (RO). At a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation to demonstrate compliance with the provider-based status criteria in effect at the time the application is submitted. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based (as long as that date is on or after October 1, 2000) until the effective date of a CMS determination that the facility or organization is not provider-based.

Facilities requesting a provider-based status determination on or after October 1, 2002 will not be covered by the provision concerning temporary treatment as provider-based in section 404(c) of BIPA. Thus, as stated in § 413.65(n), CMS ROs will make provider-based status applicable as of the earliest date on which a request for determination has been made and all requirements for provider-based status in effect as of the date of the request are shown to have been met, not on the date of the formal CMS determination. If a facility or organization does not qualify for provider-based status and CMS learns that the provider has treated the facility or organization as provider-based without having obtained a provider-based determination under applicable regulations, CMS will review all payments and may seek recovery for overpayments in accordance with the regulations at § 413.65(j), including overpayments made for the period of time between submission of the request or application for provider-based status and the issuance of a formal CMS determination.

D. Proposed Changes to Provider-Based Regulations

To fully implement the provisions of section 404 of BIPA and to codify the clarifications currently stated only

in the Q&As on provider-based status, as described above, we are proposing to revise the regulations as follows.

1. Clarification of Requirements for Adequate Cost Data and Cost Finding (§ 413.24(d)).

As part of the April 7, 2000, final rule implementing the prospective payment system for hospital outpatient services to Medicare beneficiaries, under § 413.24, Adequate Cost Data and Cost Finding, we added a new paragraph (d)(6), entitled "Management Contracts." Since publication of the final rule, we have received several questions concerning the new paragraph.

In response to these questions, we are proposing changes in wording to clarify the meaning of that paragraph. In addition, for further clarity, we are revising the coding and title of that material. Under our proposal, § 413.24(d)(6)(i) would become § 413.24(d)(6) and § 413.24(d)(6)(ii) would become § 413.24(d)(7).

As revised, paragraph (d)(6) would address the situation when the main provider in a provider-based complex purchases services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning

the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Therefore, where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the provider cannot be separately identified, the costs of the services purchased through a contract for the provider-based entity or provider department must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

For costs of services furnished to free-standing entities, we would also clarify in revised § 413.24(d)(7),

that the costs that a provider incurs to furnish services to free-standing entities with which it is associated are not allowable costs of that provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

This revision is not a change in the policy, but instead is a clarification to the policy set forth in the April 7, 2000 final rule.

2. Scope and Definitions (§ 413.65(a))

In Q/A 9 published on the CMS (Formerly, HCFA) web site at www.hcfa.gov/medlearn/provqa.htm, we identified specific types of facilities for which provider-based

determinations would not be made, since their status would not affect either Medicare payment levels or beneficiary liability. (This document may also be obtained by contacting the CMS (Formerly, HCFA) Regional Office.) The facilities identified in Q/A 9 are ambulatory Surgical Centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs); home health agencies (HHAs); skilled nursing facilities (SNFs); hospices; inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services; independent diagnostic testing facilities and any other facilities that furnish only clinical diagnostic laboratory tests; facilities furnishing only physical, occupational or speech therapy to ambulatory patients, for as long as the $1500 annual cap on coverage of physical, occupational, and speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation; and end-stage renal disease (ESRD) facilities. Determinations for ESRD facilities are made under § 413.174.

We propose to revise the regulations at § 413.65(a) to clarify that these facilities are not subject to the

provider-based requirements and that provider-based determinations will not be made for them.

3. BIPA Provisions on Grandfathering and Temporary Treatment as Provider-Based (§§ 413.65(b)(2) and (b)(5))

Current regulations at § 413.65(b)(2) state that a main provider or a facility must contact CMS (Formerly, HCFA) and the facility must be determined by CMS (Formerly, HCFA) to be provider-based before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. However, as explained earlier, sections 404(a) and (c) of BIPA require that certain facilities be grandfathered for a 2-year period, and that facilities applying between October 1, 2000 and October 1, 2002 for provider-based status with respect to a hospital be given provider-based status on a temporary basis, pending a decision on their applications. To implement these provisions, we propose to revise the regulations in § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until

October 1, 2002, and the requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), and (h) of § 413.65 will not apply to that hospital or CAH with respect to that facility until October 1, 2002. We would further state that for purposes of paragraph (b)(2), a facility will be considered to have been treated as provider-based on October 1, 2000, if on that date it either had a written determination from CMS (Formerly, HCFA) that it was provider-based as of that date, or was billing and being paid as a provider-based department or entity of the hospital.

We would also propose to add a new § 413.65(b)(2) to state that a facility for which a determination of provider-based status in relation to a hospital or CAH is requested on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS (Formerly, HCFA) determines that the facility does not qualify for provider-based status.

4. Reporting (§ 413.65(c)(1))

Current regulations at § 413.65(c) state that a main provider that creates or acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to CMS (Formerly, HCFA) if the facility or organization is located off the campus of the provider, or inclusion of the costs of the facility or organization in the provider's cost report would increase the total costs on the provider's cost report by at least 5 percent, and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status. Concern has been expressed that such reporting would duplicate the requirement for obtaining approval of a facility as provider-based before billing its services that way or including its costs on the cost report of the main provider (current § 413.65(b)(2)). To prevent any unnecessary duplicate reporting, we propose to delete the current requirement from § 413.65(c)(1). We would,

however, retain the requirement that a main provider that has had one or more facilities considered provider-based also report to CMS (Formerly, HCFA) any material change in the relationship between it and any provider-based facility, such as a change in ownership of the facility or entry into a new or different management contract that could affect the provider-based status of the facility.

5. Geographic Location Criteria (§ 413.65(d)(7))

As explained earlier in C.2 of this section, section 404(b) of BIPA mandates that facilities seeking provider-based status be considered to meet any geographic location criteria if they are located not more than 35 miles from the main campus of the hospital or CAH to which they wish to be based, or meet other specific criteria relating to their ownership and operation. To implement this provision, we propose to revise § 413.65(d)(7) to state that facility will meet provider-based location criteria if it and the main provider are located on the same campus, or if one of the following three criteria are met:

- The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider;

- The facility or organization is owned and operated by a hospital or CAH that--

(A) Is owned or operated by a unit of State or local government;

(B) Is a public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or,

(C) Is a private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services to low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan); and

(D) Has a disproportionate share adjustment (as determined under §412.106 of this chapter) greater than 11.75 percent or is described in §412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act.

- The facility meets the criteria currently set forth in § 413.65(d)(7)(i) for service to the same patient population as the main provider.

6. Notice to Beneficiaries of Coinsurance Liability (§ 413.65(g)(7))

Current regulations at § 413.65(g)(7) state that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, the hospital has a duty to provide written notice to the beneficiary, prior to the delivery of services, of the amount of the beneficiary's potential financial liability (that is, of the fact that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability). The notice must be one that the beneficiary can read and understand.

Some concern had been expressed that providing notice of a beneficiary's exact liability might be difficult in cases where the treating physician was in the process of diagnosing the patient's condition and was unsure of exactly what services might be required. In response to

this concern we clarified in the preamble to an interim final rule with comment period published on August 3, 2000 (65 FR 47670) that if the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains the fact that the beneficiary will incur a coinsurance liability to the hospital that they would not incur if the facility were not provider-based. The interim final rule preamble § 413.65(g)(7)) further explained that the hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, prior to the delivery of services, to the beneficiary's authorized representative.

We are proposing to amend § 413.65(g)(7) to include this clarifying language.

7. Clarification of Protocols for Off-Campus Departments (§ 489.24(i)(2)(ii))

Current regulations at § 489.24(i) specify the antipatient dumping obligations that hospitals have with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical conditions. These obligations are sometimes known as EMTALA obligations, after the Emergency Medical Treatment and Active Labor Act, which is the legislation that first imposed the obligations. Currently, hospitals are responsible for ensuring that personnel at their off-campus departments are trained and given appropriate protocols for the handling of emergency cases.

In the case of off-campus departments not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus before arranging an appropriate transfer to a medical facility other than the main hospital.

Some concern had been expressed that taking the time needed to make such contacts might inappropriately delay the appropriate transfer of emergency patients in cases where the patient's condition was deteriorating rapidly. In response to this concern we clarified in the preamble to

the interim final rule with comment period published on August 3, 2000 cited above (65 FR 47670) that in any case of the kind described in § 489.24(i)(2)(ii) the contact with emergency personnel at the main hospital campus should be made either concurrently with or after the actions needed to arrange an appropriate transfer, if doing otherwise would significantly jeopardize the individual's life or health. This does not relieve the off-campus department of the responsibility for making the contact, but only clarifies that the contact may be delayed in specific cases where doing otherwise would endanger a patient subject to EMTALA protection.

We are proposing to amend § 489.24(i)(2)(ii) to include this clarifying language.

8. Other Changes

In addition to the changes cited above, we are proposing to make the following conforming and clarifying changes:

- We are correcting date references in §§ 413.65(i)(1)(i) and (i)(2), in order to take into account the effective date of the current regulations.

- We are substituting "CMS" for "HCFA" throughout the revised sections of part 413, to reflect the renaming of the Health Care Financing Administration (HCFA) as the Centers for Medicare & Medicaid Services (CMS).